Effects of Individualized Health Coaching on Patients with Type 2 Diabetes

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ABSTRACT

Objective: To conduct an analysis of literature that examined the effects of individualized health coaching on hemoglobin A1c in adults with type 2 diabetes. **Methods:** A literature search of the PubMed database using the terms "goal setting" AND type 2 diabetes OR "individual counseling" was performed. Only randomized controlled trials and meta-analysis were included. **Results:** All three studies reported a statistically significant difference in lowering hemoglobin A1c levels with individualized health coaching interventions compared to the standard diabetes interventions. **Conclusion**: Health coaching should be further studied for longer amounts of time to determine the true clinical significance of lowering hemoglobin A1c. Current research shows that health coaching successfully lowers hemoglobin A1c more than standard diabetic care.

INTRODUCTION

Diabetes is the seventh leading cause of death in the United States.[1] In 2012 the total estimated amount of money spent on diabetes was $245 billion.[2] Diabetes is a major illness that can cause complications such as hypoglycemia, cardiovascular disease, stroke, depression and many others. To decrease healthcare costs and increase quality of life for the diabetic patient it is important to find the most effective way to treat diabetes to decrease rates of comorbidities and improve patient outcomes.

The most widely used test to assess diabetic status is glycated hemoglobin (HbA1c). This is a measure of the amount of glucose in a red blood cell. This provides the average blood glucose over the past 8 to 12 weeks.[3] Currently, diabetes treatment is aimed at lowering HbA1C to a target range. However, diabetes is a chronic illness that could be treated better if approached differently and this approach does not look at the patient as an individual. This approach only takes the patient's HbA1C into account, it does not consider the patient's feelings about different treatments or obstacles they may be facing as an individual.

This is where the new strategy of treating diabetes with health coaching comes in. Health coaching is a broad concept described by many different researchers. Palmer et al. describes health coaching as "the practice of health education and health promotion within a coaching context, to enhance the wellbeing of individuals and to facilitate the achievement of their health-related goals".[4] In 2006, Butterworth, Linden, McClay, and Leo described it as "a service in which providers facilitate participants in changing lifestyle-related behaviors for improved health and quality of life, or establishing and attaining health promoting goals."[5] Another article evaluated 200 definitions of health coaching and came up with a standard consensus definition: "a patient-centered approach wherein patients at least partially determine their goals, use self-discovery or active learning processes together with content education to work toward their goals, and self-monitor behaviors to increase accountability, all within the context of an interpersonal relationship with a coach. The coach is a healthcare professional trained in behavior change theory, motivational strategies, and communication techniques, which are used to assist patients to develop intrinsic motivation and obtain skills to create sustainable change for improved health and well-being."[5] These definitions can be applied to primary care providers by individualizing the patient's education and helping them to set their own personal goals by assessing their attitudes and capabilities and level of support. This includes collaboration with many different entities of health care providers, including a nurse or counselor to help the patient make their own goals that the patient feels are attainable. This also gives the patient more time to ask

questions they might not have had time to ask during the physician visit. According to a recent study the average length of time a primary care physician spends with a patient is 17.4 minutes.[6] This does not leave much time for the patient to ask questions. With health coaching the patient will have the opportunity to discuss their concerns in private counseling sessions. Recent research has shown that opportunities like this have led to improved clinical health outcomes and medication adherence.[5] The purpose of this review is to determine the efficacy of individualized health coaching on lowering HbA1c in diabetic patients.

PICO

Population: Patients with type 2 diabetes
Intervention: Individualized health coaching
Comparison: Traditional patient education
Outcome: Hemoglobin A1c

CLINICAL QUESTION

In patients with type 2 diabetes is individualized health coaching more effective than traditional patient education in lowering hemoglobin A1c?

METHODS

On September 10, 2016 a search was conducted of the PubMed database using the search terms " goal setting" AND type 2 diabetes OR "individual counseling". The filters "full text articles" and "English" and "last ten years" were used. This search returned 232 articles. These articles were screened and twenty-nine were found to be acceptable. Of the fourteen acceptable articles eleven did not include hemoglobin A1c as an outcome or included chronic diseases other than diabetes and had to be discarded. Inclusion criteria includes: meta-analysis or randomized controlled trial, written in English, published in the last 10 years, included patients with type 2 diabetes, reported hemoglobin A1c levels as an outcome, and human subjects. Exclusion criteria includes: reported data on other chronic illnesses (COPD, obesity, etc.) and did not use HbA1c as an outcome. One meta-analysis and two randomized controlled trials were used in this review. The PRISMA is shown in Figure 1, outlining how the articles were obtained.

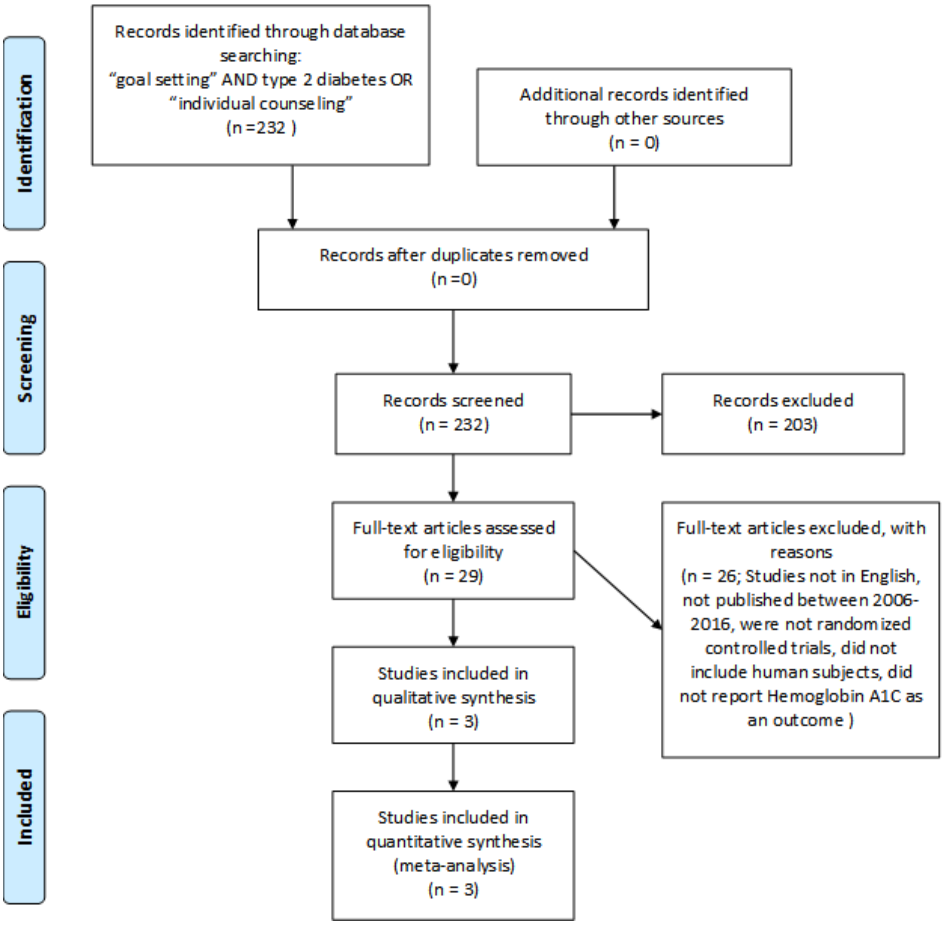

Figure 1: PRISMA outlines the method by which the articles were obtained.

RESULTS

Study 1:

Evaluating the effect of a diabetes health coach in individuals with type 2 diabetes. Sherifali et al.[7]

Objective

To assess the effects of health coaching in individuals with type 2 diabetes on hemoglobin A1c levels.

Study Design

This meta-analysis included eight randomized controlled trials published between 1946 and 2015. Search terms used included: counseling, coaching, diabetes mellitus, telemedicine, and consultations. Search strategies used were English-language, published, peer-reviewed literature. A literature search of MEDLINE, EMBASE, CINAHL, PsychINFO and the Cochrane Database of Randomized Controlled trials returned 2175 titles which were narrowed down to 526 full-text studies. Of these, eight randomized controlled trials fit the inclusion criteria. In order to be included studies had to be a randomized controlled trial, report data on subjects at least 18 years of age, report a health coaching intervention (as well as usual care of self-management education/support), be carried out by a

healthcare professional and report changes in hemoglobin A1c levels. Studies were excluded if they reported data on subjects younger than 18 years old or did not have type 2 diabetes, included data on pregnant women, health coaching was not the main intervention, did not report changes on hemoglobin A1c, or were not randomized controlled trials or used quasi-randomized methodology such as cluster randomization, or statement of consent was not obtained.

The final amount of subjects included in the trial was 724 participants. With 353 receiving a coaching intervention and 371 receiving usual care. The mean age of participants in the intervention group ranged from 53.1 to 65.8 and the percentage of females ranged from 13% to 100%. The mean duration of diabetes ranged from 2.7 to 13.1 years. Of participants in the control group the mean age ranged from 52.8 years to 65.8 years with the percentage of females ranging from 36% to 100% and mean duration of diabetes ranged from 2.7 to 13.1 years. The participant characteristics are summarized in Table 1.

Table 1: Summary of participant characteristics

	Intervention Group	**Control Group**
Mean Age	53.1 to 65.8	52.8 to 65.8
Percentage Female	13% to 100%	36% to 100%
Duration of Diabetes	2.7 to 13.1 years	2.7 to 13.1 years

A variation of health coaching strategies were used by the studies included in the Sherifali et al. A few studies used only telephone calls as their additional intervention. Other studies included nurses or other types of coaches in face-to-face meetings. Combinations of face-to-face meetings, internet and phone strategies were used in the remaining studies. Control groups received usual diabetes care and were often given support and/or educational literature. Usual care consists of traditional diabetes education and medical care. This can include information given to the patient on diet, exercise, medications or the disease of diabetes itself (i.e. disease process, long-term effects of uncontrolled diabetes or prognosis).

An overview of the randomized controlled trials included in the meta-analysis is shown in Table 2. There was a main focus spanning across the coaching interventions in each study: goal setting and attainment, increasing self-care knowledge, individualized care recommendation, and regular and frequent follow up.

Table 2: Overview of studies and interventions in Sherifali et al.[7] Abbreviations: PHC: Primary health care; NDEP: National Diabetes Education Program; NIH: National Institutes of Health; IH: interventional health

Study	**Number of Participants (Intervention:**	**Intervention**	**Control**	**Length of intervention**

	Control)			
Cinar, Schou (2014)	197 (77: 109)	Patients set goals under supervision of coach, attend coaching sessions	Traditional health education	64 weeks
Cho et al. (2011)	71 (36:35)	Specialized management by a PHC nurse	Usual care	12 weeks
Frosch et al. (2011)	201 (100:101)	24-minute DVD program with accompanying booklet, up to five telephone coaching sessions with nurse educator	20 page brochure developed by NDEP of NIH	24 weeks
Orsam et al. (2013)	56 (27: 29)	Diabetes lifestyle self-management promotion program involving remote patient reporting and automated theory-based health behavior feedback	Standard medical care	10 months
Ruggiero et al. (2010)	50 (25:25)	Two face-to-face sessions during quarterly clinic visits and four monthly telephone calls between visits	Traditional health education	26 weeks
Varney et al. (2014)	94 (47: 47)	Telephone coaching	Usual care	6 months
Whittmore et al. (2004)	53 (29: 24)	Nurse coaching intervention plus standard diabetes care	Standard diabetes care	26 weeks
Wolever et al. (2010)	56 (30:26)	IH coaching by telephone for fourteen 30-minute sessions	Usual care	26 weeks

Results

For each trial, the risk of bias was assessed and all eight studies were found to be of weak methodologic quality. This was a result of each study having unclear or high risk of bias. Reasons for risk

of bias include inadequate sample size, lack of blinding of participants and personnel, lack of blinding outcome assessment, and incomplete reporting.

To assess the degree of heterogeneity chi squared analysis and I^2 data was performed. Chi squared was 13.68 and I^2 was 49% displaying a great degree of heterogeneity. Because of this a random effects analysis was used.

Results of each study were based solely off of HbA1c results. With each study combined the overall result was a decrease in HbA1c levels of 0.32 (95 CI, -0.50 to -0.15), favoring the intervention. A forest plot of the overall results are displayed in Figure 2.

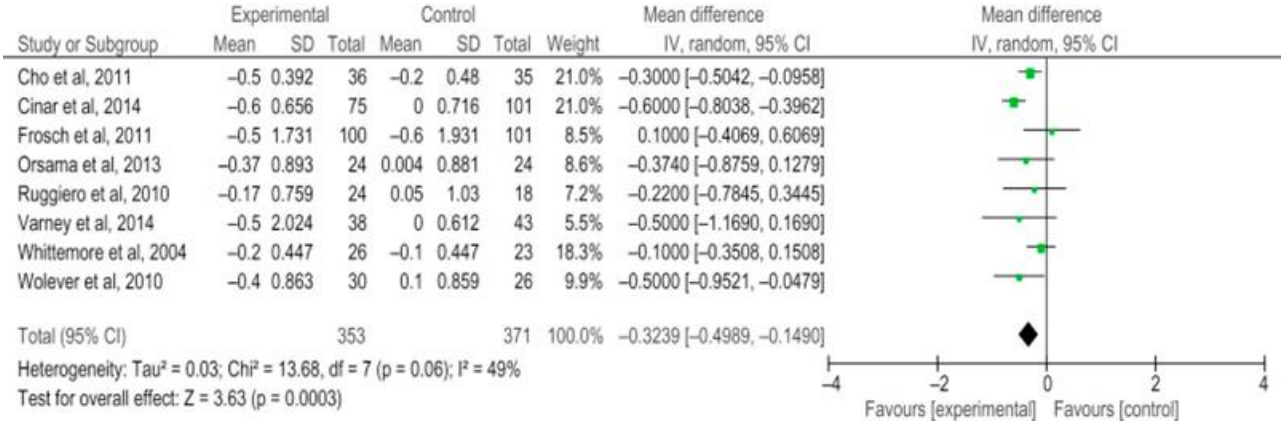

Figure 2: Forest plot displaying results of meta-analysis in Sherifali et al.

Studies were also divided into short studies (lasting less than 6 months) or long studies (lasting longer than 6 months). Six of the studies were of short duration and two were of long duration. Studies of short duration had a pooled effect of a statistically significant decrease in HbA1c levels of 0.23% (95 CI, -0.37 to -0.09). The longer studies had a pooled effect of a statistically significant decrease in HbA1 levels of 0.57% (95 CI, -0.76 to -0.38). These results are displayed in Figure 3.

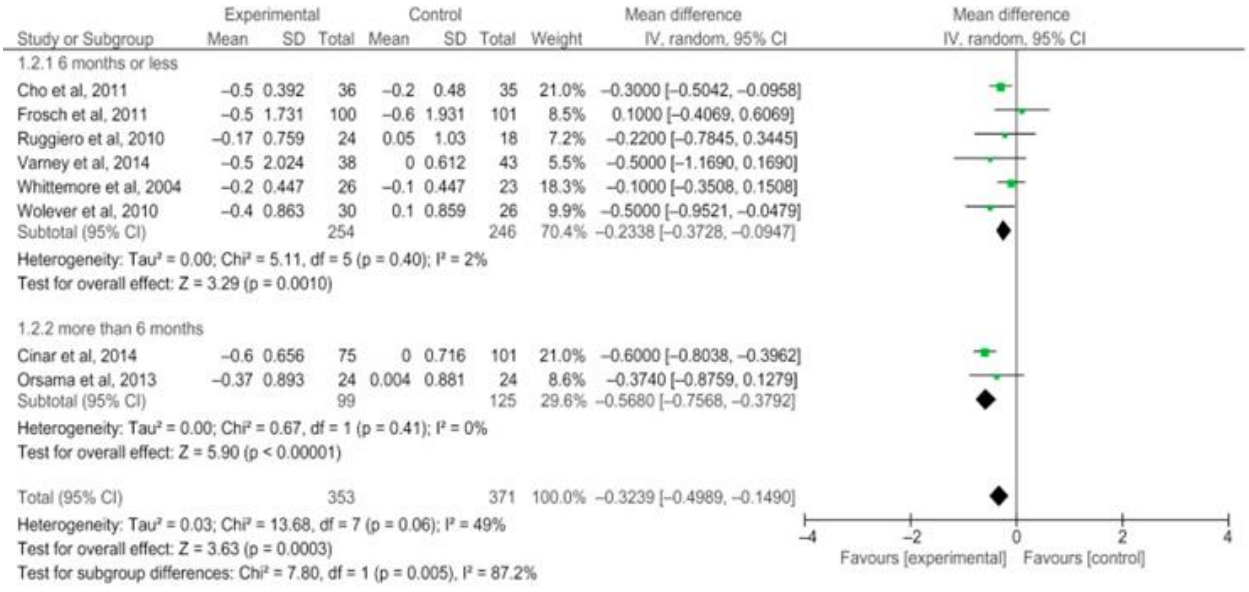

Figure 3: Forest plot showing the results when each study is divided into short (<6 months) or long (>6 months).

Study 2: *Nurse care manager collaboration with community-based physicians providing diabetes care. Hiss et al.*[8]

Objective: To determine the effectiveness of collaboration of a nurse care manager with primary care physicians to improve clinical outcomes for adults with type 2 diabetes.

Study Design:

This study was a randomized controlled trial that compared additional nurse collaboration to the physician's care alone. Adults older than 18 years old were recruited to participate in the study and given a free evaluation of their diabetes. A total of 197 adults with diabetes were recruited. The total participants were randomly assigned to a control group or an intervention. The control group participants received a report of their free diabetes evaluation in the mail. This evaluation was also sent to their primary care physician. The experimental group received a report of their evaluation as well, but were followed up with individual meetings with a nurse care manager that collaborated with their primary physician to provide continuous care to the individual.

Inclusion and exclusion criteria for the study participants were not directly mentioned. However, the population of patients were selected from two different clinics serving the underinsured in and around Detroit, Michigan and patients were required to be older than 18 years old and attend one of the two clinics within the Wayne County Department of Public Health (WCDPH). The demographics of the study participants is described in Table 3.

Table 3: Population demographics of Hiss et al.

Demographics	**Individualized Intervention**	**Control**
n (%)	95 (48)	102 (52)
Age, y	55.7 ± 13.1	57.0 ± 11.4
Male, n (%)	30 (32)	36 (36)
Ethnicity, n (%)		
White	61 (65)	68 (67)
Black	29 (31)	25 (25)

Hispanic	0 (0)	6 (6)
Other	4 (4)	2 (2)

The comprehensive exam that all patients received included the following: "diabetes and general medical history, current diabetes program, height, weight, blood pressure, foot examination, neuropathy examination, HbA1c levels, serum C- peptide, serum creatinine, lipid profile, and microalbuminuria."[8] The outcomes compared included the following: HbA1c level, cholesterol, systolic and diastolic blood pressures. In this study, the participants in the intervention group met with a nurse care manager individually at a community site to discuss goals with the patient and provide information for the patient to manage their diabetes. All of meetings were unique to each participant but each participant followed a generally guided conversation that consisted of goal setting, problem solving, and action plans to overcome the obstacles the patient was facing. This was compared to the control group, who only received diabetic literature in the mail to read at their leisure with no follow up and no health coaching. Table 4 describes exactly what each individualized intervention aimed to achieve.

Table 4: Components of the individualized Intervention:

Personal report on comprehensive (baseline) evaluation with appropriate explanations and interpretations
Problem identification with problem-specific, short-term goal setting and development of tentative action plan
Communication with primary care physician regarding initial discussions with patient; advice to patient to contact his or her physician concerning follow-up on identified problems
Collaborative interaction between nurse, physician, and patient leading to short-term goal attainment and experience for the patient as active team member
Proactive and continuous follow-up by nurse care manager

Results:

Of the 197 type 2 diabetic patients in the study, data was available on 164 following the experiment (83%). Death, refused, moved, and lost to follow up were reasons there was a decrease in post intervention data. The study used per protocol analysis, only using participants that completed the trial with the specific requirements. Both the control and the experiment group had statistically similar lost to follow up. Baselines of all measurements were taken prior to intervention and following each intervention. A two-tailed paired T test was used to determine the mean change from baseline for each outcome within each group. The following four outcomes were measured and analyzed for statistical significance: HbA1c, systolic blood pressure, diastolic blood pressure, and cholesterol.

The main outcome evaluated was change in HbA1c. There was a statistically significant improvement for HbA1c outcome in the experimental group, but not the control group (p value of .0063). These results are consistent with the idea that individualized health coaching can provide a decrease in patient's HbA1c levels. Table 5 summarizes the mean change in HbA1c and the statistical significance of each group.

Table 5: Mean change in HbA1c between intervention and control group

Intervention	**Mean Change of A1C**	**Statistical Significance**
Individualized intervention	-0.42 ± 0.15	P value = 0.0063
Basic intervention	-0.22 ± 0.17	P value = 0.20

Study 3: *Results of a successful telephonic intervention to improve diabetes control in urban adults. Walker et al.*[9]

Objective: To compare the effectiveness of the telephone coaching intervention to the conventional method of printed education in clinical outcomes for type 2 diabetics.

Study Design:

This study was a randomized controlled trial that compared outcomes in two intervention groups: telephone intervention and conventional print literature. The eligibility criteria included being over thirty years old, having a HbA1c >7.5%, being able to read and speak English or Spanish with no cognitive impairment, and taking at least one oral glucose lowering agent in the year prior to the beginning of the study.

The participants for the study were members of the health care worker union Fund in New York. Fund members include full time health workers or their spouses. The Fund primarily helped the underserved in the area, providing full coverage for prescriptions, hospitalization, lab tests, and medical office visits. A database of Fund members was used to identify eligible participants. Once identified, patients were contacted by study staff and given the opportunity to complete a screening questionnaire. No specific exclusion criteria was stated. For the most part, participants consisted of people from a minority race, low socioeconomic status, and foreign born. Of the 4548 that were assessed for eligibility, only 526 were randomized for the study. Table 6 shows a comparison between the control and experimental group.

Table 6: Population demographics of Walker et al.

Demographics	**Telephone Intervention**	**Control**
n	262	264
Age, y	55.7 ± 7.4	55.4 ± 7.2

Female (%)	68.3	65.9
Ethnicity, (%)		
White	5.7	6.1
Black	61.5	61.7
Hispanic	24.8	20.5
Other	8.0	11.7

The intervention group received phone calls from a health educator every four to six weeks for one year. During these phone calls, participants would discuss medication adherence, lifestyle changes, and goal setting. Each participant was allowed to determine what to focus on during each conversation, but all health educators followed a particular protocol. This protocol focused on self-efficacy and empowerment. Those in the control group were mailed the standard literature on diabetes education, but were not given follow up or further contact.

Hemoglobin A1c was measured twice using mail in kits before beginning the study and after the conclusion of the intervention. The kits provided each participant with instructions on how to obtain a blood sample for the participants to send to the researchers who calculated the HbA1c.

Results:

Of the 520 participants, 444 returned for follow up. Overall, the lost to follow up percentage was 15.6%, with 18.2 % lost in the experimental group and 13 % lost in the control group, with a p value of 0.10. This lost to follow up was not statistically significant between the groups. Intention to treat analysis was used in order to compensate for loss to follow up. Theintervention group showed a mean decline in HbA1c of 0.23 ± .11% after one year (P value = 0.04). The control group had a mean rise in HbA1c of 0.13 ± 13 % after one year (p value = 0.04). The authors of the study corrected for differences in sex, age, insulin use, and baseline HbA1c. The difference in the mean change in HbA1c was statistically significant at 0.40% with a p value of 0.009, favoring the use of health educator.

DISCUSSION:

Overall, each study included in this review showed a statistical significance favoring individualized health coaching. A chart comparing the characteristics and results of each study can been seen in Table 7. Study 1, by Sherifali et al. has many limitations. Only studies written in English were included in the study. There may be other studies written in other languages that were testing the same thing that might have lent use to this study that were not included. There is also great variation between the interventions in each RCT included in the meta-analysis. There is not a standardized protocol used when it comes to health coaching, so this is representative of the way this intervention has been

implemented in health care but this makes it hard to compare each study. One study (Cinar, Shou, 2014) focused on dental care and oral health. This does did not fit with the theme of the meta-analysis. Additionally, for a meta-analysis the sample size is still rather small. This could be due to the fact this is a relatively new intervention and not much research has been done on it yet. There was also a great degree of heterogeneity between each study included in this meta-analysis. This makes it hard to determine the reliability of the results.

There is unclear or high risk of bias present in each study included in this review. While the results are statistically significant it is impossible to tell how accurate they are given the high possibility of bias.

Strengths of Study 1 include that it is the first comprehensive meta-analysis of health coaching for diabetes. A review of this kind could create a push toward implementation of health coaching. Another strength is that they conducted a rigorous search with comprehensive search strategies that produced a widespread review of this relatively new topic.

Study 2 by Hiss et al. had many limitations, as well. One of the major critiques is specific exclusion criteria were not listed. The inclusion criteria were broad and unclear. Recruitment was based on individuals calling a toll-free number that was advertised by word of mouth and community posters. The study never stated if they included every person who called the number or how they decided who to include. Another limitation is this study only followed patients for 6 months which may limit the amount the education can affect the HbA1c in a short amount of time. While the results are statistically significant it is still unclear as to whether the results are clinically significant. A longer follow up would have a greater impact.

A source of bias for this study is the experimental group had meetings with a nurse care manager that were individualized to the participant's needs. An individual had the opportunity to meet with the nurse care manager as much as they wanted so it was not standardized. Without ensuring each meeting was exactly the same, some participants might have had different experiences with the study nurse and each individual could have been treated differently.

One of the strengths of Study 2 was the members of the control study group were all provided the same print materials. This allows for a consistent intervention for the control group. Another strength of the study was the intervention provided collaboration between the study nurse and the patient's original physician. This allowed more continuation of care and better management for the chronic disease. This study provides a model that further studies could use to implement health education to help improve clinical outcomes in patients with type 2 diabetes.

Study 3 by Walker et al. has many strengths and weaknesses. A limitation to this study is that the results showed that those who had over six telephone calls had a significant lowering of HbA1c, but a large number in the intervention group had less than six telephone calls. This can affect the overall power of the study, because there was not a large number of participants in the group that showed statistical significance. The final limitation is that there was loss to follow up with both the post survey of the study and the post intervention HbA1c measurement. This also contributes to decreased power within the study.

A source of bias in Study 3 is the HbA1c was obtained via a mail-in kit. Without this population being medically trained, these results may be skewed due to collection techniques differing for each participant. Another concern includes the short length of the study which could have led to outcome

bias is that the intervention only lasted 12 months. This intervention includes using a telephone conversation to coach a patient to help improve their diabetes. The intervention in this study may also require more time due to the fact a telephone call is more impersonal than an in person conversation.

One strength of Study 3 was the population was homogenous in that there was no discrepancy in obtaining medications or seeking medical treatment. All participants were provided everything free of charge which limited the influence that socio-economic status could have on the outcome of the study. Overall, the population was very diverse, bringing people of many different backgrounds and races. Another strength of the study is that the study group fit the desired population that could potentially benefit from the telephonic intervention, because it is both easy and accessible for this population.

Table 7: An overview comparison of all health coaching studies:

	Sherifali, et al.[7]	Hiss, et al.[8]	Walker, et al.[9]
Number of patients	724	197	526
Intervention: Control	371:353	95:102	262:264
Average age (years)	52.8 to 65.8	Control: 57.0 ± 11.4 Intervention: 55.7 ± 13.1	55.5 ± 7.3
Average duration of diabetes	2.7 to 13.1 years	7.4 ± 7.3-7.4	9.2 ± 6.6
Average follow up	3 - 16 months	6 months	12 month
Intervention	Variety of interventions	Individualized nurse care manager	Telephone calls for health coaching
Results (change from baseline, HbA1c)	-0.32 (95% CI, -0.50 to -0.15)	-0.42 ± 0.15	-0.23 ± 0.11%
Statistically significant	P value = 0.003	P value = 0.0063	P value = 0.04

CONCLUSION:

The studies compiled above all show statistical significance in lowering patient's HbA1c by using individualized health coaching compared to the control group of standard diabetic education. Further studies should follow patients for a longer amount of time. The biggest weakness of each study was that the patients were not being evaluated for a long enough time. More longitudinal studies would be helpful for tracking HbA1c over a longer periods of time. HbA1c is a measurement to track progress over three months. If there was more time for the individualized health coaching, there may be more time for the HbA1c to change as a result. Both randomized controlled trials had lost to follow up and both authors addressed this in their statistical analysis. It was determined the lost to follow up was not significant and did not affect the final outcome of the studies. Further studies must also address what

component of the individualized health coaching make it successful. All the research had varied methods in which they provided health coaching. This makes it hard for clinicians to implement a specific program. Finding which technique is most effective would make health coaching more efficient, successful and easier for clinicians to implement. The final improvement further studies could include would be more consistent and accurate follow up. Many studies were excluded from this review because they did not include HbA1c as a clinical outcome. As this is the way diabetes is followed, having a more controlled follow up for each study with similar outcomes being measured would carry more statistical and clinical significance.

In the end, the statistical significance of change in HbA1c has to correlate to clinical significance in order to implement it into practice. The changes in HbA1c of -0.32, -0.42 and -0.23 in Sherifali, et al, Hiss, et al., and Walker, et al., respectively, is not enough to be considered clinically significant. This is why more studies need to be done for longer periods of time. Longer studies could determine if changes could be clinically significant if given a longer chance to work. However, health coaching isn't meant to replace treatment by medication. It is meant to enhance it. If there is a change of 0.42% in 6 months on top of changes that a drug would cause then it could be clinically significant.

The above studies all show a decrease in HbA1c with the intervention group indicating that there is some relationship between the intervention and outcome. Variables that cannot be controlled in these studies determines whether or not the intervention of health coaching is the actual cause of lowering HbA1c. These studies show it is the education and coaching that the patient is getting that is causing the HbA1c to decrease, but it cannot be certain the improvement is solely from the coaching and not just from spending more time with the patient. There are many variables that could be a part of why health coaching is successful in lowering HbA1c.

Larger scale studies with longer experiment timelines could provide the results needed to push forward. When determining if health coaching is beneficial to type 2 diabetics, doctors and patients must ask if the increased time and money required to provide good coaching is worth the end result of improved diabetic care. Type 2 diabetes is spreading like an epidemic across the United States. Millions of dollars and millions of lives are affected every day and the rates do not appear to be slowing down. This proves there is a need for more effective diabetes treatments. More research should be done but this review proves that current research shows individualized health coaching statistically lowers HbA1c's and is an option worth pursuing.

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